

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 02-512V

June 18, 2007

CARL BELLOTTI,

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Petitioner,

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v.

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Hepatitis B vaccination followed
seven days later by GBS; also a
URI during this period of time

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SECRETARY OF THE DEPARTMENT OF
HEALTH AND HUMAN SERVICES,

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Respondent.

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ORDER TO SHOW CAUSE¹

Petitioner filed a petition dated May 21, 2002, under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., alleging that hepatitis B vaccine administered on November 30, 2000 and January 4, 2001 caused Guillain-Barre Syndrome (GBS). Petitioner alleges that shortly after his first hepatitis vaccination, he had numbness in his feet and thigh and

¹ Because this order contains a reasoned explanation for the special master's action in this case, the special master intends to post this order on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would clearly be an unwarranted invasion of privacy. When such a decision or designated substantive order is filed, petitioner has 14 days to identify and move to delete such information prior to the document's disclosure. If the special master, upon review, agrees that the identified material fits within the banned categories listed above, the special master shall delete such material from public access.

he was fatigued. He had a cold as well. Dr. P.C. Gilmore opined that the cause of petitioner's GBS was hepatitis B vaccine.

Respondent is ORDERED TO SHOW CAUSE by **July 31, 2007** why this case should not proceed to damages.

FACTS

Petitioner was born on June 4, 1954.

He received his first hepatitis B vaccination on November 30, 2000. Med. recs. at Ex. 1, p. 1.

On December 18, 2000, petitioner saw Dr. Todd B. Orvald, an orthopedist, for lumbar radicular syndrome secondary to disc extrusion and prolapse at L4-L5 with probable congenital shortened pedicle syndrome with stenosis. Med. recs. at Ex. 21, p. 20. Petitioner's left buttock area was painful and he had tingling to his left foot. *Id.*

He received his second hepatitis B vaccination on January 4, 2001. Med. recs. at Ex. 1, p. 1.

On January 16, 2001, petitioner went to the emergency department of Yakima Valley Memorial Hospital where he saw Dr. Gregory A. Freed. Med. recs. at Ex. 8, p. 2. Petitioner had an upper respiratory infection for the prior five or six weeks that he did not seem able to get over. He had nasal congestion and scratchy throat for a period of weeks, perhaps as long as six weeks. *Id.*

On January 16, 2001, Dr. A.W. Janjua wrote that petitioner had a clear-cut history of upper respiratory tract infection five to six weeks prior to admission, and the possibility of GBS. Med. recs. at Ex. 10, p. 7.

On January 16, 2001, petitioner was admitted from the emergency department of Yakima Valley Memorial Hospital with a history of pins and needles sensation in the arms and legs for five days prior to admission and weakness in the arms and legs three days prior to admission. Med. recs. at Ex. 4, p. 2. He had an upper respiratory tract infection for about five to six weeks prior to admission. *Id.*

On January 16, 2001, Dr. S.R. Khamisani wrote that petitioner had flu-like symptoms continuing until that day and he started having cold-like symptoms about five or six weeks earlier. Med. recs. at Ex. 7, p. 1.

On January 26, 2001, petitioner was discharged from the hospital. Dr. B.J. Hamon wrote the discharge summary, finding petitioner had GBS. Med. recs. at Ex. 10, p. 12.

On January 26, 2001, Dr. P.C. Gilmore, a neurologist, opined that petitioner had a fairly minor upper respiratory infection six weeks before the onset of his GBS. Petitioner's neurologic symptoms began on January 11, 2001. Initial records noted he had been experiencing a prolonged upper respiratory infection prior to the development of his GBS, but this was not accurate. Petitioner experienced very minimal cold symptoms, probably about six weeks previously and mainly at night. They resolved totally a few days before onset of his GBS. His first hepatitis B vaccination was about one month previously and afterwards, he noted a tingling-like feeling in his legs which he attributed to a low back condition. Med. recs. at Ex. 2, p. 1. The upper respiratory infection was a possible cause of his GBS. Petitioner also received two hepatitis B vaccinations. In comparing the upper respiratory infection and the vaccinations, Dr. Gilmore's opinion was that the hepatitis B vaccine was the most probable cause. Med. recs. at Ex. 2, p. 2.

On April 2, 2001, petitioner returned to Dr. Torvold, having recovered from GBS. Med. recs. at Ex. 21, p. 18. Petitioner got off and on the examining table and toe walked and heel walked. He had brisk patellar and Achilles reflexes, no motor weakness with hip flexion, abduction and adduction, knee flexion and extension, dorsiflexion and plantar flexion. *Id.*

DISCUSSION

This is a causation in fact case. To satisfy his burden of proving causation in fact, petitioner must offer "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen v. Secretary of HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005). In Althen, the Federal Circuit quoted its opinion in Grant v. Secretary of HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992):

A persuasive medical theory is demonstrated by "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[.]" the logical sequence being supported by "reputable medical or scientific explanation[.]" *i.e.*, "evidence in the form of scientific studies or expert medical testimony[.]"

In Capizzano v. Secretary of HHS, 440 F.3d 1274, 1325 (Fed. Cir. 2006), the Federal Circuit said "we conclude that requiring either epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect is contrary to what we said in Althen...."

Without more, "evidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." Grant, 956 F.2d at 1149. Mere temporal

association is not sufficient to prove causation in fact. Hasler v. US, 718 F.2d 202, 205 (6th Cir. 1983), cert. denied, 469 U.S. 817 (1984).

Petitioner must show not only that but for the vaccine, he would not have had GBS, but also that the vaccine was a substantial factor in bringing about his GBS. Shyface v. Secretary of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

In Gilbert v. Secretary of HHS, No. 04-455V, 2006 WL 1006612 (Fed. Cl. Spec. Mstr. Mar. 30, 2006), the undersigned ruled that hepatitis B vaccine can cause GBS and did so in that case. Respondent's expert, Dr. Roland Martin, testified that the appropriate onset interval, if a vaccination were to cause an acute reaction, would be a few days to three to four weeks. *Id.* at *18. In the instant action, petitioner's onset of GBS was seven days, which fits well within the appropriate temporal time frame for a vaccine reaction.

The Federal Circuit in Capizzano emphasized the importance of the opinions of treating physicians. In Capizzano, four of Mrs. Capizzano's treating physicians viewed her rheumatoid arthritis as caused by hepatitis B vaccine. 440 F.3d at 1326. In the instant action, Dr. Gilmore opined that petitioner's hepatitis B vaccinations were more likely the cause of his GBS than his prior upper respiratory infection.

Respondent's expert Dr. Arthur Safran opined on September 18, 2002 that hepatitis B vaccine does not cause GBS and that petitioner's upper respiratory infection was far more likely to be the cause of his GBS. R. Ex. B. Dr. Safran wrote his opinion before the Omnibus proceeding on hepatitis B vaccine and demyelinating diseases. The Omnibus proceeding is now over and the undersigned has ruled in petitioner's favor on the issue of can hepatitis B vaccine cause GBS. Respondent may want to alter respondent's position on this issue.

As for the upper respiratory infection, admittedly Dr. Gilmore did not state his basis for selecting the vaccine over the upper respiratory infection as the cause of petitioner's GBS. On the other hand, both the upper respiratory infection and the vaccine could be significant factors in causing petitioner's GBS. See Shyface.

The undersigned is not prepared to say that there was positive rechallenge after the second vaccination because the tingling that petitioner experienced after the first vaccination was attributed to his lumbar radicular problem by Dr. Torvald (who also opined that petitioner recovered from his GBS in April 2001, just three months after onset; the Vaccine Act requires petitioner to have residua of his vaccine injury for more than six months in order to receive compensation—42 U.S.C. §300aa-11(c)(1)(D)(i)).

This case may be worth doing a low litigative risk settlement. Respondent is ORDERED TO SHOW CAUSE why this case should not proceed to damages by **July 31, 2007**.

IT IS SO ORDERED.

DATE

Laura D. Millman
Special Master